Amendments to the Drawings:

It was noted by the Applicant that drawings 4-6 and 7A-7D did not have reference

numerals despite such reference numerals being in the specification. Accordingly, the Applicant

is submitting herewith corrected drawings having reference numerals.

Attachment: Replacement Sheet

Annotated Sheet Showing Changes

5

REMARKS/ARGUMENTS

Claims 1-19 are currently pending in this Application. In an Office Action mailed June 13, 2006, claims 1-19 were rejected.

In this Response, the Applicant has cancelled claims 1-14, amended claims 15-19 and added claim 20. New claim 20 is fully supported by the specification as filed and does not add new matter. Accordingly, the Applicant requests reconsideration of the rejections in light of the above amendments and these remarks.

DRAWINGS

The drawings were objected to because they purportedly failed to show every feature of the claimed invention. Specifically, the drawings were objected to because they failed to show the "medical insertion device" of claim 19. Claim 19, as amended, no longer has language directed towards a "medical insertion device," and accordingly, the Applicant submits that the objection to the drawings should be overcome.

It was also noted by the Applicant that drawings 4-6 and 7A-7D did not have reference numerals despite such reference numerals being in the specification. Accordingly, the Applicant is submitting herewith corrected drawings having reference numerals. This does not add new matter.

REJECTIONS

Claim 19 was rejected under 35 U.S.C. § 112 as purportedly failing to comply with the enablement requirement. Claims 1-14 were rejected under § 102(b) as purportedly being anticipated by Bonutti (U.S. Pat. No. 6,338,730). Claim 19 was also rejected under § 102(b) as purportedly being anticipated by Klein (U.S. Pat. No.6,517,533). Claims 15-18 were rejected under § 103(a) as purportedly being unpatentable over Bonutti ('730) in view of certain other

prior art references. The Applicant requests reconsideration of the rejections in view of the following comments.

REJECTIONS § 112

While not agreeing with the Office Action's contentions, and as noted above, to expedite the prosecution of this application the Applicant has deleted the language "medical insertion device" from the claims. Thus, the Applicant deems this rejection to be moot.

REJECTIONS § 102

The Applicant has cancelled claims 1-14 and thus these claims require no comment. However, with respect to the rejection of claim 19, the Applicant respectfully traverses the rejection.

Claim 19 was rejected under § 102(b) as purportedly being anticipated by Klein (U.S. Pat. No.6,517,533). While claim 19 has been amended to better define what the Applicant deems to be the invention, the Applicant will still comment on the reference.

Klein does not disclose the presently claimed invention. Specifically, Klein discloses a suture delivery apparatus. See, e.g., '553 patent, Title, Abstract, col. 2, lines 49-53. Klein does not disclose, for example, a delivery apparatus having a withdrawal mechanism proximate the channel, which is configured to cooperate with a retraction head of the trocar or cannula. The Office Action cites to nothing in the reference that discloses this limitation. Accordingly, Klein cannot be said to anticipate claim 19.

REJECTIONS § 103

Claims 15-18 were rejected under § 103(a) as purportedly being unpatentable over Bonutti ('730) in view of certain other prior art references. The Applicant submits that the

Office Action failed to meet its burden for the various rejections combining Bonutti with the other references.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. MPEP § 2143.

Specifically, the Office Action fails to provide any motivation or suggestion to modify Bonutti or combine Bonutti with any of the other references.

The Office Action states, for example,

It would have been obvious at the time of the invention to one of ordinary skill in the art to modify the disclosure of Bonutti et al. with the structural teachings of Dibelius to provide an expandable cannula with rigid elements in a helix shape.

Office Action, Para. 19. See also, Paras. 34, 29 and 24. Even if the combination does disclose all of the limitations of the claims, that is not enough to meet the requirements for a prima facie rejection under § 103. None of these statements explain any *motivation* to modify; rather, they state that the combination, as suggested, of the prior art purportedly discloses all of the elements of the claims. *In re Rouffet*, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457-58 (Fed. Cir. 1998) (The combination of the references taught every element of the claimed invention, however without a motivation to combine, a rejection based on a *prima facie* case of obvious was held improper). The level of skill in the art cannot be relied upon to provide the suggestion to combine references. *Al-Site Corp. v. VSI Int'l Inc.*, 174 F.3d 1308, 50 USPQ2d 1161 (Fed. Cir. 1999). *See also*, MPEP § 2143.01. The mere fact that references <u>can</u> be combined or modified

does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990).

The Applicant submits that the Office Action with respect to Claims 15-18 has failed to meet the burden to establish a prima facie case of obviousness. Accordingly, the Applicant submits that the rejection should be overcome.

Moreover, one of ordinary skill in the art would not be motivated to combine Bonutti ('730) with any of the cited references. First, Bonutti '730 teaches that the use of a trocar should be limited and a trocar used with a cannula *only when needed*. See col. 7 lines 6-7 (emphasis added). Accordingly, one of ordinary skill in the art would not look to modify Bonutti ('730) with any reference that requires a trocar.

The references Kim '852, Kim '318, and Dibelius '883 all disclose various cannulas which have a substantially uniform diameter. Cannulas with a uniform diameter would require a trocar for insertion to minimize damage to a patient upon insertion of the cannulas. Thus, the cannulas of references Kim '852, Kim '318, and Dibelius '883 would require the use of a trocar. Since, Bonutti '730 expressly discourages the use of a trocar, one of ordinary skill in the art would not be motivated to combine Bonutti '730 with Kim '852, Kim '318, and Dibelius '883.

Additionally, the Office Action states that Kim '318 discloses a ribbon spring comprising a rigid element in the form of a helix, as claimed in claim 17. The Applicant respectfully traverses that Kim '318 discloses a ribbon spring in the shape of a helix. Rather, Kim '318, in Figure 7, discloses a rigid element in the form of a spiral with teeth on the outer surface. See col. 3 lines 49-60. The ribbon spring as claimed is a helix member. While a ribbon spring does spiral around the member (see Application Fig. 5), the ribbon spring also has a helix shape. There is nothing in the disclosure of Kim '318 that identifies the rigid member as forming a

helix. Accordingly, the Applicant submits that Kim '318 does not disclose a ribbon spring as claimed.

Accordingly, in view of the above, Applicant submits that all pending claims are now in condition for allowance and respectfully request reconsideration of the rejections and passage to issue.

Should anything further be required, a telephone call to the undersigned at (312) 226-1818 is respectfully invited.

Respectfully submitted,

FACTOR & LAKE, LTD

Dated: December 13, 2006

Jody L. Factor/ Reg. No. 341,87

One of Attorneys for Applicant

CERTIFICATE OF MAILING

I hereby certify that this AMENDMENT AND REPLY TO THE OFFICE ACTION MAILED ON JUNE 13, 2006 is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on December 13, 2006.

Yolanda Solis